**Attachment 2B**

# Objective 3 - Clinical Follow up Questionnaire

**Incident HIV/Hepatitis B Virus infections in South African blood donors:**

**Behavioral risk factors, genotypes and biological characterization of early infection**

**OMB Number: 0925-XXXX Expiration Date:**

# Objective 3 - Clinical Follow up Questionnaire

**OMB Number: 0925-XXXX Expiration Date:**

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx\*). Do not return the completed form to this address.

***This section of the form is to be completed by the research assistant or other research staff.***

A1. Subject ID ***(Internal study number to be assigned by Study Management System)***

\_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

A2. Subject Donor Number ***(Number that will link with donor’s Meditech info)*** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

A3. Location of Study Visit. ***(Blood collection site neumonic (clinic site code). The neumonic can be mapped back to Branch, Zone or Province – this will have to be coded during analysis phase)***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

A4. Date of Study Visit (DD/MM/YYYY)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

A5. Research Staff Initials: \_\_ \_\_ \_\_ \_\_ \_\_

**Current MEdical Status**

B1. Since your last visit for participation in this study have you gone to your doctor or sought medical care at a clinic or hospital?

0 No ***Skip to B2***

1 Yes

97 Don't Know

98 Refuse to Answer

B1a. If yes, what was the reason for seeking medical care? \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

B2. Since your last visit for participation in this study have you gone to a traditional healer?

0 No ***Skip to B3***

1 Yes

97 Don't Know

98 Refuse to Answer

B2a. If yes, what was the reason for seeing the traditional healer? \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

B3. Since your last study visit have you had a cold, flu, or any other infection?

0 No ***Skip to B4***

1 Yes

97 Don't Know

98 Refuse to Answer

B3a. If yes, what symptoms did you have? Please list all the symptoms you can think of such as headache, fever, body pain, chills, vomiting, diarrhea, or any other symptom that you may have had. \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

B4. Since your last study visit have you started taking antiretroviral medicines, also known as ARVs?

0 No ***Skip to B6***

1 Yes

97 Don't Know

98 Refuse to Answer

B4a. What are the names of the antiretroviral (ARV) medicines you are currently taking? \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

To help trigger your memory, please look at the placard with pictures of medicines and then place a check mark in the box next to the medications that look like the ones you are taking:

|  |  |
| --- | --- |
| Place √ if taking this medication | Medication |
|  | AZT – Zidovudine |
|  | ddI – Didanosine |
|  | 3TC – Lamivudine |
|  | D4T – Stavudine |
|  | ABC – Abacavir |
|  | TDF – Tenofovir |
|  | FTC - Emtricitabine |
|  | IDV - Indinavir |
|  | NVP – Nevirapine |
|  | EFV – Efavirenz |
|  | ETV - Etravirine |
|  | ATV – Atazanavir |
|  | LPV/r – Lopinavir/Ritonavir |
|  | RAL - Raltegravir |
|  | SQV - Saquinavir |
|  | OTH – Other not pictured |

B5. If yes, have you had any side effects from taking your current antiretroviral (ARV) medicines?

0 No

1 Yes

97 Don't Know

98 Refuse to Answer

B5a. If yes, what side effects did you have? Please list all the side effect you can think of, such as nausea, loss of appetite, vomiting, diarrhea, or any other symptom that you may have had. \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

B5b. Did you miss taking some or all of the doses of your current antiretroviral (ARV) medicines because of the side effects you experienced?

0 No

1 Yes

97 Don't Know

98 Refuse to Answer

B6. Are you currently taking anything else for your health such as vitamins, herbs, supplements or natural medicines?

0 No

1 Yes

97 Don't Know

98 Refuse to Answer

B6a. If yes, please list the name(s) of each vitamin, herb, supplement you are taking? \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_\_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

B7. Since your last study visit have you started taking traditional medicines that were recommended or provided by a traditional healer?

0 No

1 Yes

97 Don't Know

98 Refuse to Answer

B7a. If yes, please list the names of traditional medicines you are taking? \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

B7b. If yes, have you had any side effects from taking these traditional medicines?

0 No

1 Yes

97 Don't Know

98 Refuse to Answer

B7c. If yes, what side effects did you have? Please list all the side effect you can think of, such as nausea, loss of appetite, vomiting, diarrhea, or any other symptom that you may have had. \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

B8. (Ask of Women Only) Are you currently pregnant?

0 No

1 Yes

96 Not applicable, never been pregnant

97 Don't Know

98 Refuse to Answer

***Thank you for taking the time to complete this questionnaire. Please return this questionnaire to the research staff. If you have any questions or concerns, please talk to the research assistant or nurse. You can also contact the medical director at our blood bank.***

# Placard Showing Antiretroviral Therapy Pictures

